International Pharmaceutical Excipients Council
Of The Americas

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Chairman

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Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0278 Proposed Regulations for Prior Notice of Imported Food Shipments Under the Public Health Security and Bioterrorism Preparedness and Response Act 0f 2002

Dear Sirs:

The following comments are submitted on behalf of the International Pharmaceutical Excipients Council of the Americas (IPEC-Americas). IPEC-Americas is an industry trade association formed in 1991 whose members are companies which either manufacture excipients or are firms which use them in dietary supplements and finished pharmaceutical dosage forms. As the agency is aware, many excipients used in these products are food additives or food ingredients and some, such as gelatin and starches, frequently may be present in food or drugs in the same physical grade. Some materials also have uses outside the food and pharmaceutical industries, e.g. as adhesives (starches and gums), as fillers (silica and other inorganic materials), etc. that would not require either registration or prior notification of intent to import.

In addition, a number of member companies of both types regularly import materials affected by the regulations either from outside manufacturing or brokerage sources, or from their own foreign affiliates. Since pharmaceutical use typically is only a small percentage of an average excipient's total usage, overseas suppliers, even those which are subsidiaries of member companies, seldom know how their products will be used or in what kind of product. As a result, IPEC-Americas members are greatly affected by the proposed regulations and we appreciate the opportunity to provide comments.

We hope our comments and suggestions will be helpful, as we fully support the Agency's intent and the goal of the proposed regulations to protect the U.S. food supply. Given the global nature of the food and food ingredient industries, this is no easy task.

It is because of this and the fact that few companies which supply excipients can be certain about the ultimate use of their material at the time of importation that gives us and our members great concern. For example, it would seem prudent for IPEC-Americas members to assure themselves that the producers of all imported materials and their manufacturing facilities are properly registered under the Act and all product trade names are correctly identified in timely prior import notification notices. This would extend to those materials, which they, acting as an

02N-0278 C 208

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importer, might subsequently elect to use or sell for use in finished drugs. To do otherwise would seem to expose an importing company to possible future liability or at least denied entry of the material. In our opinion, this "requirement" represents a significant burden and a huge allocation of company resources for a market sector that traditionally has only been required to register normal importation notification with the U.S. Customs Service. However, in the current circumstances we acknowledge that something needs to be done and are hopeful that reasonable application of both the registration and prior import notification procedure will assist the Agency to better monitor the situation while allowing industry to efficiently conduct its business as normally as possible.

In the experience of IPEC-Americas members, shipments of pharmaceutical excipients or food ingredients generally come into the United States in one of four ways, whether by ship or airfreight. Each will be discussed separately below.

1. Whole containers of one particular material for delivery to one customer/address in the United States.

   In this example, under the proposed regulations, the only requirements should be to register the site of manufacture and to submit one prior notice for the shipment (together with the relevant documents for the US Customs Service). Neither is viewed as a problem.

2. A container with several products from one manufacturing site destined for delivery to one customer/address in the United States.

   In this instance, the site would be required to be registered. However, there would also appear to be a requirement under the proposed regulations for individual notifications for each product, even though they originate in the same plant and are going to the same address. This would seem to be overly burdensome. We respectfully submit that both the letter and spirit of the intent of the legislation would be equally served by allowing multiple entries on one notification document. This would reduce the amount of paperwork required for the shipment, and would also reduce the amount of repetitive information required.

3. Smaller, not containerized, shipments of one or more materials for delivery to one customer/address in the United States. Such shipments would include most airfreight shipments.

   Here, each manufacturing site would have to be registered, and there would need to be a separate notification for each individual shipment, as in the first example, since the materials will be single shipments.

4. Single consolidated container loads which include several shipments of different materials intended for numerous customers/delivery addresses in the United States which are consolidated at or near the port of embarkation and then delivered to a forwarding agent in the United States. After entry into the United States, the container contents are broken down into individual shipments for delivery to the appropriate customers/addresses.

This situation also represents a difficult case. Consolidation of loads in a single container is a common practice for the delivery of less-than-container-sized loads. Food ingredients and pharmaceutical excipients are sometimes shipped this way. However, the contents of such containers need not be restricted to food or pharmaceutical ingredients, other inert materials may also be included, but these materials would not require notification of shipment or manufacturing site registration since they would not be intended for use in the manufacture of food or pharmaceutical products. Obviously, the agent responsible for consolidating the load would have responsibility for compiling the documents, etc. However, there would also be a burden on the ingredient manufacturer and the importer to ensure that the necessary paperwork was correct. This would be critical since if the shipment is rejected for any reason, it would appear that the entire contents would be banned from entry into the United States then and in the future.

We also note there is a declared intent to eventually consolidate the food ingredient notice of shipping with the USCS notification at some stage in the future. Presumably there would also be a similar intent with the pharmaceutical excipient notification system. IPEC-Americas suggests that much time and effort could be saved, by both industry and the government agencies, by having one joint set of forms covering all three notification systems; in effect having one form allowing multiple entries for materials and sites of manufacture that could be used to notify the Agency of the intent to import food ingredients or pharmaceutical excipients, and could also be used to notify USCS.

Thank you for the opportunity to comment on the proposed regulations.

Yours sincerely,

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